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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,848	11/07/2001	William A. McMillan	22660-0019 DIV 3	1015

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EXAMINER

REDDING, DAVID A

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/006,848

Applicant(s)

MCMILLAN ET AL.

Examiner

David A Redding

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's argument's concerning the restriction mailed March 12, 2004 are persuasive and accordingly the restriction is withdrawn. The non-elected claims 12-21 are rejoined with claims 1-11 and have been examined on the merits.

### *Double Patenting*

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-3,12-17, are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,391,541 in view of USP 6,168,948 (Anderson et al.). The claims of the instant application are silent as to a flow controller and waste chamber. The Anderson et al. patent discloses the use of flow controllers (618, figure 6a) and waste chamber (414, fig.4a-c) in a device similar to the device of the instant claims.

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Accordingly, it would have been obvious to one skilled in the art to incorporate a flow controller and waste chamber into the claims of the instant application in view of the known use disclosed in Anderson et al.

4. Claims 4-11, 18-24, are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application No. 09/800,590 in view of USP 6,168,948 B1. The claims of the instant application are silent as to a step of directing waste to a waste chamber. The Anderson et al. patent discloses the use of flow controllers (618, figure 6a) and waste chamber (414, fig.4a-c) in a device similar to the device of the instant claims.

Accordingly, it would have been obvious to one skilled in the art to incorporate a step of directing waste to a waste chamber into the claims of the instant application in view of the known use disclosed in Anderson et al.

This is a provisional obviousness-type double patenting rejection.

5. Claims 1-3, 12-17, are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 09/970,434 in view of USP 6,168,948 B1. The instant claims are silent as to a waste chamber and third reaction chamber. The Anderson et al. patent discloses a similar device to that claimed with waste chamber (414) and third reaction chamber (402) for performing DNA analysis (PCR).

This is a provisional obviousness-type double patenting rejection.

6. Claims 4-11,18-21, are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 54-136,215-230 of copending Application No. 10/005,685.

This is a provisional obviousness-type double patenting rejection.

The instant claims do not specify that the filter is a size exclusion filter. However, such function is inherent in view of the disclosure of the instant application.

7. Claims 1-3,12-17, are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 10/006,904 in view of USP 6,168,948 B1. The '904 claims are silent as to an ultrasonic transducer. The Anderson et al. patent discloses a similar device to that of the '904 application with the use of ultrasonic agitation (col.7, lines 18-21). Accordingly, it would have been obvious to one skilled in the art to add an ultrasonic transducer to the device of claims 1-4 of application '904 in view of the know use in the Anderson et al. patent.

This is a provisional obviousness-type double patenting rejection.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-21, are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 6,168,948 B1 (Anderson et al.) in view of 5,374,522 (Murphy et al.).

The Anderson patent discloses a microfluidic device (figure 3) which reads on the claimed cartridge. The Anderson et al. device consists of microfluidic channels and chambers in fluid communication formed in a silica chip or wafer (lab on a chip). A general description of the device is given in col. 17, line 40 thru col. 24, line 13. Figure 3 illustrates one embodiment used for performing DNA amplification methods.

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The device comprises a sample collection port (202) which is considered to be equivalent to the claimed inlet port. The port (202) leads to a second reaction chamber (206) in which it is disclosed that cells are lysed in order to remove the DNA. The Anderson et al. patent discloses that lysis can be initiated by ultrasonic agitation (col.7, lines 18-21). The structure for creating the ultrasonic energy is illustrated in figure 28 (col. 42, lines 4-31). After lysing, the patent discloses that it is desirable to separate (filter) the DNA from the cellular debris (col. 7, lines 23-30; col. 37, lines 37-44). Accordingly, a filter is placed either at the entrance to channel (208) or in the channel (208). The Anderson et al. patent is silent as to the ultrasonic transducer being coupled to a wall of the lysing chamber or the use of beads in the lysing chamber.

The Murphy et al. patent discloses a method of lysing cells in order to release DNA comprising adding micro-beads to the cellular solution and subjecting the solution to sonication by contact with a sonicator. Accordingly, it would have been obvious to one skilled in the art that the ultrasonic transducer with beads of the Murphy et al. patent be used in place of or in combination with the ultrasonic transducer (figure 28) in the Anderson et al. patent, especially in view of the disclosed use for lysing cells.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Redding whose telephone number is 571-272-1276. The examiner can normally be reached on Mon.-Fri. 6:00 - 3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D.A.R.

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